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SUPREME COURT, U.S.

88-611

NO. _____

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1988

TIMOTHY SCOTT ROMAN
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF LOS ANGELES
Respondent

THE PEOPLE OF THE STATE OF CALIFORNIA, BY THEIR ATTORNEY, IRA REINER, THE DISTRICT ATTORNEY FOR THE COUNTY OF LOS ANGELES
Real Party in Interest.

PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF CALIFORNIA

TIMOTHY SCOTT ROMAN
(PRISONER 8875112/Hall of Justice)
In propria persona
c/o CHESTER LEO SMITH
12301 Wilshire Blvd. #303
Los Angeles, CA 90025
(213) 476-6486

I. QUESTIONS PRESENTED

This Petition should be considered now because **Timothy Roman** (as a dwarfed child treated with contaminated growth hormone under an experimental NIH program) precipitates immediate consideration of clear and present dangers confronting **homo sapiens:**

1. **DOES THE** UNITED STATES CONSTITUTION (ART. XIV) PROSCRIBE STATE CRIMINAL PROSECUTION OF THE SUBJECT OF A DEFECTIVE FEDERAL (NIH) MEDICAL EXPERIMENT FOR AN INTENT CRIME WHERE THE FEDERAL EXPERIMENT WAS DESIGNED TO AFFECT THE FUNCTIONING OF THE BRAIN? ... **And this raises the issue:**

2. **HOW TO** PROVIDE ADVANCE FEDERAL CONSTITUTIONAL PROTECTION (ART. V) FOR MEDICAL EXPERIMENTEES IN AN ETHICAL

MANNER UNDER THE NUREMBERG CODE WHERE NIH SPECIALISTS ARE UNABLE TO CONDUCT ESSENTIAL RESEARCH FOR SPECIES SURVIVAL BECAUSE THEY CANNOT PROVIDE ADVANCED AGREED MEDICAL AND LEGAL PROTECTION **IF THE EXPERIMENT FAILS** ... FAILURE BEING STATISTICALLY INEVITABLE GIVEN THE COMPLICATED TERMS OF THE HUMAN EXISTENCE ON THIS PLANET.

II. LIST OF PARTIES

Petitioner is **Timothy Scott Roman,** in propria persona. He is defendant in State of Calfornia Los Angeles County Superior Court felony action No. A 815 402 filed 12/11/86. He is Prisoner Number 8875112, now in the Los Angeles County Hall of Justice, awaiting trial on a charge of first degree murder.

Respondent, Ira Reiner, is the District Attorney, County of Los Angeles.

Respondent is the Superior Court of the State of California for the County of Los Angeles.

Also served: The Supreme Court of the State of California.

The constitutionality of the prosecution of Petitioner under the California Penal Code is in question. 28 U.S.C.#2403(b) may be applicable. Also served: John Van de Camp, Attorney General of the State of California.

Information parties served include: SECRETARY OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES c/o: The Solicitor General of the United States, Department of Justice, Washington, D.C. 20530.

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SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF LOS ANGELES
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THE PEOPLE OF THE STATE OF CALIFORNIA, BY THEIR ATTORNEY, IRA REINER, THE DISTRICT ATTORNEY FOR THE COUNTY OF LOS ANGELES
Real Party in Interest.

PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF CALIFORNIA

The Petitioner Timothy Scott Roman respectfully prays a writ of certiorari issue to review the judgment of the Supreme Court of the State of California entered 7/20/88 denying without opinion his Petition for Review.

OPINION BELOW

There was no opinion. The Petition for Review And Stay was denied. (Appendix A-1)

JURISDICTION

Jurisdiction is invoked under the United States Constitution Article V, Article VI, and Article XIV.

CONSTITUTIONAL PROVISIONS INVOLVED

United States Constitution, Art. V

United States Constitution, Art. VI

United States Constituion, Art. XIV

STATEMENT OF THE CASE

Petitioner has been accused by the State of California of the First Degree murder on the evening of 12/10/86, of his mother, Susan Roman. He has been detained on such charge since 12/10/86.

Petitioner entered a written plea of not guilty and not guilty by reason of insanity. Pre-trial motions have been in progress. At a hearing on 2/5/88 defendant submitted to the Court a duly served: 'Request To Take Judicial Notice/Motion for Continuance/Or Dismiss Under 14th Amendment/ (Appendix A-3 to A-19).

The essence of the motion was that the defendant, born a dwarf, was a victim of a well-intentioned but failed Federal NIH Medical experiment using natural

growth hormone obtained from cadavers (APPENDIX B1 to B18 - NIH FACT SHEET No. 86 2793 published May, 1986, entitled HUMAN GROWTH HORMONE AND CREUTZFELDT-JAKOB DISEASE). Further: The only evidence is that the best of the NIH cannot and almost certainly will never be able to determine the effects of such failed medical experiment on the brain and physical condition of the 10,000 the subject of this experiment ... (Appendix B13 to B18) and as a consequence defendant can never receive a fair or speedy trial where he could present factual evidence as to this NIH disaster - and as a matter of law he should be declared to be developmentally disabled under the relevant state statute.

On March 7, 1988, the Motion to

Dismiss of defendant on Stated Constitutional Grounds was denied by the Judge Presiding, Department H, Superior Court, Van Nuys, Criminial Case No. A 815402, Los Angeles County Superior Court. [The Trial Court at all times carefully permitted defendant to make a proper record].

Prohibition was denied 6/2/88 by the Court of Appeal (Second Appellate District, Los Angeles) (App-A-2). Petition for Review was denied July 20, 1988, by the Supreme Court of the State of California. (App-A-1).

Medical History

Petitioner is a member of the class of 10,000 mostly dwarfed children treated from 1963 to 1985 with National Institutes of Health supplied natural

Growth Hormone (from pituitary glands removed from hundreds of thousands of cadavers) under a NIH National Hormone and Pituitary Program (NHPP) that commenced in 1963 and continued to 1985. See Appendix B-1 to B-21 as to this tragedy that befell children who, to qualify initially for admission to the right to receive this priceless nGH, had to be the nation's sickest children.

Mr. Roman was born in 1964. He was so treated under the NIH program (by thrice weekly injections of nGH) from 1970 to 1985. Mr. Roman then was on this Federal program for 15 of its 22 years, receiving nGH derived from over 400,000 cadavers. In 1985 the program was ordered stopped after several of the 10,000 died of a neurological slow virus

disease known as Creutzfeldt-Jakob disease (CJD). CJD is a rare disease of older age occurring in adults in their mid-50's at an average rate of one in one million adults. It is also known as "KURU" in New Guinea, where its tribal victims die in a "burst" many years after a feast on the brains of slain enemies.

The NIH had to conclude the laboratory protocols under which the cadaver derived hormone was supposedly 'purified' of mutagens had to have been defective [Appendix B1 to B8] - and the ultimate fear is a "burst".

The only mutagen so far known to have been transmitted, CJD, is considered one of the group of transmissible degenerative encephalopathies; has never been visualized by electron miscroscopy;

is always fatal; there is no certain test to detect if one is infected; it has a reputed incubation period of 20 to 30 years; it destroys connecting brain tissues (relevant to a defense of grand mal seizures); testing of animals at NIH has produced no results as yet.

The NIH has contracted (by Westat, Inc.) [App. B13] a 60 month study of the locatable children but not to conclude until 1992. Westat Inc. has a response rate to date in locating the children of only some thirty percent.

This clearly never to be repeated experiment has raised the human CJD transmissible base in the United States ("two-fold to thirty-fold") by adding the 10,000 to a base that in 1980 caused only 142 deaths from CJD. (**Iatrogenic**

Creutzfeldt-Jakob disease. Elizabeth Rappaport, M.D. (former medical officer FDA). Neurology. September 1987). [App. B19 to B21]

Statistically the unknown virus of CJD will now certainly cross AIDS with unknown match-up, but, if a match, viral hell. **Arguendo**, the Westat study to set up tracking is not producing workable scope since there is not any financial encouragment (e.g. advance provision of medical tests and care for participants in the study) for participants, to offset the distasteful chore of answering sickening inquiries and participating in a life long study of when you are going to 'maybe' die. Defendant receives no provision for medical care from the NIH.

The Trial Court was also requested

to take judicial notice of United States District Court (Central District, California) Action No. CV -87 08706 (HLH) (BX) (Appendix A-22 to A-30) (a class action filed by Mr. Roman to obtain medical care for the class of 10,000) ...

Petitioner has no plain or speedy or adequate remedy to obtain evidence that even the NIH cannot obtain.

For one clear example, the Westat Inc. contract is only in about the 24th month of a 60 month contracted study period by the Centers for Disease Conduct] (Appendix B14).

California Penal Code Sections 25 and 29 exclude evidence of 'mental illness, disease or defect ...' and in essence under the law the burden is on defendant to show developmental

disability or insanity. But defendant cannot produce evidence of facts the NIH cannot determine.

Thus: At the age of six, the Petitioner, a dwarfed sick child, was entrusted to adult scientists for medical experimentation. For 15 years he received thrice weekly experimental injections under a Federal NIH program, derived from the tissue of over 400,000 cadavers and designed to act directly on his already defective brain. He is now threatened with the incalculable results of a well intentioned medical experiment the subject of disastrous miscalculations by those adult scientists. No trier of fact can determine a truth that cannot be determined by the National Institutes of Health.

REASONS FOR GRANTING THE WRIT

1. United States et al v. Stanley et al, (107 Sup. Ct. Rptr. 3054)(1987) shows the Supreme Court considers human experiments a class for which particular (equitable) relief may be appropriate - and that the Nuremberg Code should be binding not only in this case on this medical experimentee, but for other Federal medical experimentees.

There is relevant language in Stanley (P. 4171) re experimentation if injunctive relief were the issue.

"... experimentation with unconsenting soldiers, like any constitutional violation, may be enjoined if and when discovered. An injunction, however, comes too late for those already injured; for the victims, 'it is damages or

nothing."

(Page 4168) **(Justice Brennan)**

"Before addressing the legal questions presented, it is important to place the Government's conduct in historical context. The medical trials at Nuremberg in 1947 deeply impressed the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the **Nuremberg Code** as a standard against which to judge German Scientists who experimented with human subjects. Its first principle was:

> **"1. The voluntary consent of the human subject is absolutely essential.**
>
> The duty and responsibility for ascertaining **the quality of**

> the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.' **United States v. Brandt (The Medical Case)**, 2 Trials of War Criminals Before the Nueremberg Military Tribunals Under Control Council Law No. 10, pp. 181 -182 (1949) (emphasis added).

Justice Brennen quotes (in Footnote 2 on page 4168):

> "(Human experimentation authorized by the State) dramatizes the notion that the State is free to treat its nationals in the manner it chooses

because it perceives itself as the source of all rights, and therefore as beyond the reach of law, rather than regarding rights as inalienable, that is, not subject to arbitrary cancellation by the State." Bassiouni, Baffes, Evrard, **An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation, 72 J. of Crim. L. & C. 1597, 1607 (1981).**

Comment: **The 10,000 were all children.** Mr. Roman was age 6 when he became an experiment. A parent "consented". This is not such a 'quality of consent' which relieves the State of its responsibility to its **human experimental children.** The relief Mr. Roman asks is that the State not

'arbitrarily cancel' his existence as the experiment which he still truly is. He asks in effect for injunctive relief from a prosecution which will take away his liberty when the State has conceivably changed the terms of his DNA and RNA messengers by injections of cells from hundreds of thousands of cadavers, then denied it has any 'personal duty and responsibility' to assist him when he has the impossible task of presenting a coherent defense to a criminal charge which could deprive him forever of life as a free human being.

Justice O'Connor (P.4165):

"No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case.

Indeed, as JUSTICE BRENNAN observes, the United States military played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, . . . and the standards that the Nuernberg Military Tribunals developed to judge the behavior of the defendants stated that the 'voluntary consent of the human subject is absolutely essential. . . to satisfy moral, ethical and legal concepts. **United States v. Brandt** (The Medical Case), 2 Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10, p. 181 (1949).

By whatever name it is called, the 10,000 need medical and legal protection

until time can sort out 'moral, ethical, and legal concepts' arising from such a thicket of miscalculation by adults dealing with our sickest children.

The application of any State Penal Code should be constitutionally limited with reference to the tiny class of Federal Human Medical Experimentees where the experiment has proven defective. Such experiments (and on children) are an inevitable and absolute necessity for the survival of the species. Some of the experiments inevitably will fail. Attention should be paid to how society will handle the medical and legal problems of such experimentees.

It is easy to diminish the consequences of this particular medical experiment since the slow viruses

involved are aptly named, working away for decades before their fulfilled greeting. CJD has no test.
Just possibly, if you killed defendant, and opened his brain up, you might see some of the typical 'spongiform' consequences.

At Appendix B-12 is the May, 1988, listing of an assembly of Federal specialists who cannot determine what has happened to the children.

2. In the absence of Federal Legislation, the Federal Courts have a duty to provide appropriate injunctive relief for members of this class as Federal Medical experimentees.

Reference is made to minutes of the May, 1988, meeting of the CJD NIH Committee (Appendix B10). It

shows (P. 12) the epidemiological survey is still in progress. It shows (P.14) hGH recipients are now excluded from blood or tissue donations.

The Federal Government does not know what it has done. This is why the 10,000 are a special class.

To a reasonable certainty the 10,000 are a Federal human medical experiment which has resulted in experimentees with an array of potential diseases of unknown types and diverse effects. . . The 10,000 are viewed by the best the NIH has as a special class, unique in this country, subject to unknown risks as a result of this experiment.

This class of Federally created experimentees should have coherent due

process protection - and **must be** encouraged [by e.g. guarantees of medical care] to participate in long term studies that may be essential for species survival (Appendix A22 to A30), so this group can be closely followed for the best interests of society and the group.

3. The Nuremberg Code (as to human medical experimentees) is binding on the State and Federal Courts of the United States.

This Code was applied by the United States to condemn Nazi scientists.

The history of the 20th Century establishes beyond any reasonable doubt that it is the mark of the beast to abandon (without medical care) your medical experimentees. History mandates our acceptance of reciprocity to achieve

world minimal standard of ethics as to our own human experimentees.

The Federal Government never obtained the 'voluntary consent' of Mr. Roman (a child). Under the Nuremberg Code the Federal Government cannot delegate to the State of California its 'personal duty and responsiblity' to Mr. Roman. If anyone tries Mr. Roman, it should be a Federal Court with direct control of Federal employees and records.

The Nuremberg Code mandates exclusive Federal jurisdiction over this actual class of failed Federal medical experimentees.

Further, absent Federal legislation or 5th Amendment protection developed by this Court, the NIH specialists are also unable to conduct essential research for

species survival since they are unable to experiment on living human beings in an ethical manner because they are incapable of providing for advance agreed legal and medical protection of those on whom experiments are done, if an experiment fails, as is statistically inevitable.

There is a clear and present danger confronting **homo sapiens** (from deadly and unknown and unseeable viruses) which requires constant **and now** experimentation on human beings (including children) to meet the necessities of the very survival of the species.

The conception of the Constitution, and its amendments, is that various govermental stations have been established to cover the immense array of possible human problems - so that at

least one of such stations would be available and capable of recognizing and presenting a temporary solution to some key human question inserted by random chance into that particular station. Historically, the legal system has been the insertion point for key random human questions. Compare: **Dreyfus.**

Human experimentees should be constitutionally protected in advance by coherent medical and legal protection (as per the structure proposed at Appendix A35 to A43) from the inevitable misadventures that will occur in the best planned of experiments, recognizing always that, 'human nature being what it is' and that, random chance being the basic law of the **origin of species**, the 'misadventure' may be the only '**X**' part

of an experiment which has medical and societal value (Compare: **Penicillin**), an '**X**' value which, properly recognized for further study, may be a random key to species survival.

Compare: **The Theory Of Games.** Von Neumann and Morgenstern (Princeton University Press.

It is possible this '**X**' could be Mr. Roman.

It is more than possible one of the 10,000 could be such an '**X**', given the uniqueness of this event in human history with 10,000 beings for a first time ever injected with scores of thousands of cells from cadavers.

Thus, the words of an original:

> "No doubt it is possible, as Mr. G. H. Lewes has argued, that at the first commencement of life many different forms were evolved; but if so we may conclude that only a very few have left modified descendants. For, as I have recently remarked in regard to the members of each great kingdom, such as the Vertebrata, Articulata ... we have distinct evidence in their embryological homologous and rudimentary structure that within each kingdom all the members are descended <u>from a single progenitor</u>."

CONCLUSION

For these reasons a writ of certiorari should issue to review the judgment and opinion of the Supreme Court of the State of California, and

A peremptory writ of mandate should issue directing and compelling the said Supreme Court to vacate its order denying petitioner's Petition, and granting the motion of defendant to dismiss this prosecution under the 14th Amendment and the 6th Amendment in that defendant, as a failed Federal medical experiment which has had unknown and unknowable consequences on his brain, can never have a fair or speedy trial, and that the defendant should be declared as a matter of law to be developmentally disabled within the meaning of 42 USCS 6001(7) of

the Developmental Disabilities Act of 1984, and the laws of the State of California enacted and subject thereto (W. & Ins. 4512 et seq.) - so that the Penal Code of the State of California should be construed as subject to the intent of 42 USCS 60001, et seq..

The relief prayed for should be granted so that a known human medical experiment is protected, and society can still benefit from the fact petitioner is a member of a class which is a continuing medical experiment, certainly and uniquely unto the issue since **most mutations seem to be recessive and thus tend to be masked for generations.**

Respectfully

TIMOTHY SCOTT ROMAN

APPENDIX A

A-1	Denial by Supreme Court
A-2	Denial by Court of Appeal
A-3 to A-19	Motion(s) of defendant denied by Trial Court
A-20 to A-21	Request to Take Judicial Notice to Trial Court
A-22 to A-30	First Amended Complaint No. CV - 87 08706 District Court Central District California (As relevant)

A 1

ORDER DENYING REVIEW

AFTER JUDGMENT BY THE COURT OF APPEAL

2nd District, Division 1, No. B033714

S006042

IN THE SUPREME COURT OF

THE STATE OF CALIFORNIA

IN BANK

TIMOTHY SCOTT ROMAN, Petitioner

SUPERIOR COURT OF THE COUNTY

OF LOS ANGELES, Respondent;

PEOPLE, Real Party in Interest

Application for stay DENIED

Petition for review DENIED

{SUPREME COURT FILED JULY 20, 1988}

KAUFMAN

Acting Chief Justice

A 2

STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

ROBERT N. WILSON, CLERK

DIVISION: 1 DATE: 06/02/88

CHESTER LEO SMITH

12301 Wilshire Blvd

Suite 303

Los Angeles, CA 90025

RE: **Roman, Timothy Scott**

vs.

S.C.L.A.

The People State of California

2 Criminal

Los Angeles No. A 815 402

THE COURT:

The petition for Writ of Mandate is denied.

A 3

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, vs. TIMOTHY SCOTT ROMAN Defendant	) NO. A815402) NOTICE OF MOTIONS OF DEFENDANTS/ RE 1538.5 MOTION TO DISMISS/RE MOTION TO CONTINUE) DATE:2/5/88) TIME:10:00AM) DEPT:H

TO THE DISTRICT ATTORNEY:

You are notified that the Motions of defendants entitled:

The 1538.5 Motion.

Motion to Dismiss under Amend. VI and XIV of the U.S. Constitution; and Cal. Const. Art. I, 13;

Motion, in the alternative, to continue the hearing of the 1538.5 to await further qualified detailed evidence from the National Institutes of Health relevant to the physical and mental and genetic effect on defendant of the described Federal Experiment (or until receipt of an unqualified admission from the Director of the NIH and the relevant Committe(s) concerned with the nGH children) that the NIH does not know and never can know the effects of this failed experiment on the actions and capacities and DNA (germ cells) of defendant and the other children similarly treated.

These Motions will be heard on 5 February 1988, in Department "H" (Honorable Richard Kolostian) at 10:00 AM, or at such other date as the Court hears argument thereon.

A copy of the said Motions (and Declaration of Chester Leo Smith in support and Points and Authorities) was served on you personally on January 28, 1988.

The motion may be supplemented by other documentation/ Points and Authorities/ or oral argument/ since Federal Court action No. 87-08706 HLH (BX) (of which the Court is requested to take Judicial Notice) is an in process proceeding. Also, by such other and further oral and documentary evidence as may be heard at the time of said motions.

These Motions will be heard on 5 February 1988, in Department "H" (Honorable Richard Kolostian) at 10:00 AM, or at such other date as the Court hears argument thereon.

A copy of the said Motions (and Declaration of Chester Leo Smith in support and Points and Authorities) was served on you personally on 1/28/88.

The motion may be supplemented by other documentation/ Points and Authorities/ or oral argument/ since Federal Court action No. 87-08706 HLH (BX) (of which the Court is requested to take Judicial Notice) is an in process proceeding. Also, by such other and further oral and documentary evidence as may be heard at the time of said motions. //CHESTER LEO SMITH-Counsel for Defendant

DECLARATION OF

CHESTER LEO SMITH

IN SUPPORT OF ALL MOTIONS

NOTICED ON 5 February 1988

I am the attorney for defendant. It is submitted:

The testimony before this Court (and all the Exhibits) substantiate the allegations in support of the 1538.5 motion, also the motion to dismiss and the motion in the alternative to continue, also the essential allegations of the Federal Court Complaint.

The Doctors (Doctor Kaplan, Doctor Lippe) testified they relied on the National Institute of Health for the information as to the CJD matter, and contaminated nGH.

The NIH has in process the stated 60 month study.

At least 40 months remain of that study.

There are not even any NIH animal test results as yet. It is believed published standard reference works establish that usually mutations, if any, appear in the issue of the living members of homo sapiens. It cannot be established from available released statements of the NIH, but it is believed that their specialists, when directly asked, should confirm that the known facts indicate, to a reasonable certainty, that in the case of the 10,000 the germ cells (still alive) and mutations from said germ cells, of cadavers have gone, statistically, with

unknown and undeterminable effect, into at least some of the 10,000, and certainly those in the program for many years.

This should reasonably, statistically, include Mr. Roman who was on the program for 15 of the 22 years of the program - far longer than most of the children.

One neurological disability involved (called CJD) has an roughly estimated incubation period of 10 to 30 years. The records of the NIH offered into evidence show other diseases, known and unknown, may be involved.

Mr. Roman took the nGH from 1970 to 1985 (which was 15/22 of a program that commenced in 1963). Arithmetically he has an almost certain result of having been injected in a failed NIH experiment

(at the very least) with a deadly never seen virus that ultimately destroys the brain. There is no known test. It has never been determined when the neurological damage starts.

It is submitted:

It is a denial of due process under the 14th Amendment to prosecute Mr. Roman for an alleged intent crime under these circumstances. Defendant is incapable of presenting evidence (that would be relevant to the issues in the 1538.5 motion) because of the circumstances of this failed Federal medical experiment.

This case of the 10,000, including Mr. Roman, is distinguishable from any other event in history of homo sapiens in that this was a medical experiment,

totally under the control of the Federal Government and its NIH specialists, with-wholly honorable objectives, and wholly disastrous consequences specifically magnified by the known introduction into the brains of at least some of the 10,000 (and to a near statistical certainty, into the brain of Mr. Roman) of the DNA/RNA of deadly live viruses (taken from hundreds of thousands of cadavers). This live (or activated) DNA/RNA had/has the capacity to change the DNA of e.g. Mr. Roman, with unknown consequences for genetic coding of the physical and mental processes of Mr. Roman - as well as causing neurological deficits which eat his brain slowly into death.

All needs of society are protected

by the relief requested in the Federal Court Action. It can certainly be assumed the NIH will not duplicate the history of other medical experiments of human history wherein the experimentors failed to provide medical care and treatment and protection for the experimentees after the conclusion of the experiment (See: Auschwitz in England - Stein & Day) (See: Dering v. Uris 1962. No. 1281 High Court of Justice. Queen's Bench Division) - and that the NIH will substantiate in unequivocal form the allegations of the complaint by clear and convincing evidence, including specifically what can never be known as to the effect on the genetic (DNA) of the experimentees.

Reference is made to each and all of the exhibits (and testimony of all witnesses) offered in support of the 1538.5 Motion by defendant or the people, and all said oral and written evidence as offered in support hereof. Such evidence is offered again herein, subject to the exclusion of any evidence ordered suppressed unless the Court considers it relevant, overall, to the issues in these motions. . . . So declared under penalty of perjury at Los Angeles, California on this day of January, 1988.

Respectfully

By: //SS//

Chester Leo Smith

POINTS AND AUTHORITIES

The title of these Motions is ...

1538.5 Motion.

Motion to Dismiss under Amend. VI and XIV of the U.S. Constitution; and Cal. Const. Art. I, 13;

In the alternative, to continue the hearing of the 1538.5 to await further qualified detailed evidence from the National Institutes of Health relevant to the physical and mental and genetic effect on defendant of the described Federal Experiment (or until receipt or an unqualified admission from the Director of the NIH and the relevant Committe(s) concerned With the nGH children) that the NIH does not know and

never can know the effects of this failed experiment on the actions and capacities and DNA (germ cells) of defendant and the other children similarly treated.)

Defendant moves to dismiss this action under Article VI and XIV of the Constitution of the United States (and Cal. Const. Art. I, 13) for reasons as stated in the Motion, the Declaration of Chester Leo Smith, the evidence, and in the Federal Court Complaint, and in that the court in all events, after considering the evidence, can reasonably conclude that the defendant cannot have a fair and speedy trial as is his Constitutional right and is a victim of the failed Federal Medical experiment described in the Federal Complaint, and

in the alternative defendant moves to continue the hearing of the 1538.5 motion to permit such evidence (affirmative or negative)to be obtained from the National Institute of Health.

The position of defendant is that he cannot ever have a Fair Trial and a Speedy Trial because of the inability to obtain evidence in a reasonable time frame and in a reasonably coherent manner so it could be intelligently presented to a trier of fact where the primary evidence is solely within the control of the Federal Government and where the evidence shows and will show totally unknown and undeterminable effects of such medical experiment on the mental and physical condition of Mr. Roman and also on his DNA, and manner of genetic

coding). These genetic coding deficits and changes in DNA [plus past history of grand mal seizures as testified to by Dr. Lippe] would include his control over physical movements and his capacity to give messages to his hands and feet and eyes and brain, etc., as to what they should or should not do.

The issues herein include (as to the 1538.5):

Capacity to legally "consent" and to legally "withdraw consent".

It is submitted the medical evidence (plus that of the NIH experiment) shows Timothy Roman could never give coherent consent to any search or respond in a coherent manner to any questions, [including because his brain was always floating in a sea of

medications affecting his capacity to remember, concentrate, think in any short term or long term way] and all evidence should be suppressed.

Also: Can the People under any circumstances show the required elements of the crime of first degree murder with which defendant is charged where this failed Federal medical experiment had known and unknown and never-possible-to-be-known effects on the DNA/germ cells/coding of Mr. Roman, and where to a reasonable certainty, his 15 years in a program that lasted 22 years inserted almost certainly into his brain deadly viruses [by Federal mistake] which have been and are progressively destroying, over a period of many years, the cells of his brain,

but in a manner that cannot be tested until death and autopsy.

It is submitted that the People cannot show the required elements of any crime under the undisputed evidence.

Respectfully submitted, . . .

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

vs.

TIMOTHY SCOTT ROMAN

Defendant.

CASE NO A.

REQUEST TO TAKE JUDICIAL NOTICE

(Ev. Cd. 450-455)

DATE: 5 February 1988

TIME: 10:00 A.M.

DEPT: H

This defendant respectfully moves the court to take judicial notice of the following Federal Court action.

Reference is made to Action No. 87 08706 HLH (BX), United States District

Court, For the Central District of California, entitled Timothy Roman (etc.) v. Secretary of Health (etc.). This was filed December 31, 1987. The Court is requested to take Judicial Notice thereof under Evidence Code Sections 450 to 455. A copy of said action was delivered to the Court and a copy was also delivered to the People (Office of District Attorney/Assistant D.A. Brad Stone) in the first week of January, 1988. For Reference a copy of this Federal Court action will be the last exhibit number to be identified in the record, after all other exhibits are offered.

Defendant also offers the Declaration of Chester Leo Smith . . . .

CHESTER LEO SMITH

Attorney for Defendant

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

TIMOTHY SCOTT ROMAN	)	No. CV - 87 08706
	)	
Plaintiff (s)	)	FIRST AMENDED
vs.	)	COMPLAINT:
SECRETARY OF HEALTH	)	FOR MEDICAL
	)	TREATMENT OF
	)	FEDERAL MEDICAL
_____	)	EXPERIMENTEES

COMPLAINT

Mr. Roman alleges by attorney, Chester Leo Smith:

JURISDICTION

1. This is a civil action under the Constitution and laws of the United States. Jurisdiction is invoked as follows:

A. Under Amendments I, V, VI, VIII, XIV to the United States Constitution. Also Art. I, Section 8 of U.S. Constitution.

B. Under 42 USCS 6000, et seq (The Development Disabilities Act of 1984).

C. Claims for relief (including

those against the District Attorney of the County of Los Angeles, also the Superior Court of the State of California, also the State of California) are cognizable by the Court pursuant to 28 USCS 1331 and 1332. Also 42 USCS 1981 and 1983 and 1985 and 1986 and 1988. Also 28 USCS 2283, 2284 ....

B. Plaintiff alleges undisputed facts show he and each member of the class of 10,00 are failed biological experiments of the Federal Goverment under a Federal NIH experiment conducted from 1963 to 1985 using contaminated growth hormone (derived from improperly purified human pituitary glands) injected into each of the 10,000.

C. It is alleged each of the 10,00 is now in fact sufffering great and

immediate irreparable injury (in all aspects of their existence as human beings) that cannot ever be eliminated from all such aspects of their human existence since the known facts show the Federal Government (and NIH) cannot now and never will be reasonably able to determine the extent and nature of the neurological and other diseses and physical and mental damge inflicted on the 10,000.

D. The reason is the growth hormone (derived from over 600,00 cadavers) was contaminated with one or more slow viruses or other unknown disease entities, with an incubation period of 10 to 30 years, so confusing in origin and nature that the NIH has commissioned a 60 month study (P. 48 to

61 attached) but only as a beginning to determine what action might be taken - that it is not known in any respect by any NIH or other scientist if any action can be taken other than to bury the dead if, as, and when they die.

E. Each of the 10,000 are entitled to a legal determination they have a constitutional right at least to be provided medical treatment by the Secretary since the history of the 20th Century establishes beyond any reasonable doubt that abandonment without medical treatment of human medical experimentees is a mark of the beast . . . [Footnote Two]

Footnote Two:

Auschwitz in England, MacGibbons and Kee. London 1965. Account of libel trial of Dering v. Uris (1962), High Court of Justice, Queen's Bench Division, (Case No. 1281). Selected pages re abandonment of human medical experimentees are p. 64 to 75 sequentially (Also Ex. p. 1083 to 1094). This fully reported trial involved Ausehwitz medical experiments conducted from 1942 - 1945 by Doctors Dering, Clauberg, Schumann. See In Re Dr. Horst Schumann (Extradition proceedings S.S. Doctor Horst Shumann to West Germany from Ghana 1966, obtained in 1969 by counsel for Mr. Roman. Ex. P. 775 to 789 ...) ...

The cost of all permanent diability payments - in that it is requested the Court determine each of the 10,000 is to have the right to elect to be deemed permanently disabled as a matter of law for the remainder of their lives within the meaning of the definition thereof of the Social Security Administration.

The cost of specialized education and specialized job training . . . .

CLASS ACTION

ALLEGATION:

For the purpose of declaratory, injunctive and mandamus relief only this suit is brought as a class action pursuant to Rule 23(a) of the Federal Rules of Civil Procedure, and is maintainable under Rule 23(b) (1) (A),

23(b) (2), and 23(b)(3) . . . . separate actions by individual members of the class would create the risk of inconsistent or varying adjudications and would establish incompatible standards for the conduct of the responsibilities of the Federal government to the class.

The size of the class is known. Original government documents heretofore estimated the class at about 10,000 ... The location of each member of the class is now the subject of a government study by a private contractee, Westat Inc. The class can be notified through Westat, Inc.

WHEREFORE, plaintiffs pray judgment as follows:

1. That plaintiff Timothy Scott Roman, and the other members of the class

of 10,000, are entitled to lifetime medical care ....

2. For certification of the class of 10,000, and with the requested orders.

3. That the Developmental Disabilities Act of 1984 is an appropriate basic concept to use to protect the Constitutional rights of known Federal Medical Experimentees (such as the class of 10,000), as well as the rights of society.

4. For perpetuation of testimony on such conditions as the Court deems proper.

5. For an order restraining the prosecution of Mr. Roman by the State of California in the crime now charged.

6. For any other equitable or declaratory judgment proper. . . .

VERIFICATION

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I have read the foregoing PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF CALIFORNIA and know its contents.

I am THE DEFENDANT PETITIONER. The matters stated in the foregoing document are true of my own knowledge except as to those matters which are stated on information and belief, and as to those matters I believe them to be true. Each and all of the documents referred to have been provided by my counsel of record in the criminal proceedings in the State of California, and I have directed him to

attach and provide same in proper form, and directed him to cause this Petition to be served in compliance with the Rules of the Supreme Court.

Executed on September 15, 1988, at Los Angeles, California. I declare under of perjury under the laws of the State of California that the foregoing is true and correct.

TIMOTHY SCOTT ROMAN

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELS

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 12301 Wilshire Boulevard, Suite 303, Los Angeles, California 90025.

I served the following document described as

PETITION FOR WRIT OF CERTIORARI
TO THE SUPREME COURT OF THE
STATE OF CALIFORNIA

on September 16, 1988, in this action by placing true copies thereof, including three copies whenever required, enclosed in sealed envelopes as stated on the attached mailing list:

See attached service list

I am not at this time a member of the bar of this Court.

BY MAIL I caused such envelope with postage theron fully prepaid to be placed in the United State mail at Los Angeles, California. I declare I am a member of the bar of the State of California, and mailed copies at the direction of Mr. Roman, Petitioner herein, AND TO COMPLY WITH THE Rules of the Supreme Court, including Rule 28.

CHESTER LEO SMITH

SERVICE LIST

The Supreme Court of the State of California
3580 Wilshire Blvd.
Room 213
Los Angeles, California 90010

Mr. Ira Reiner
The District Attorney of the County of Los Angeles
210 West Temple Street
Los Angeles, California 90012

Mr. Brad Stone
Assistant District Attorney
Courthouse
6230 Sylmar Avenue
Los Angeles, California 91401

The Honorable Richard Kolostian
Judge Presiding, Department H
Courthouse
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The Secretary of Health and Human Services
c/o The Solicitor General
Department of Justice
Washington D.C., Washington 20530

The Honorable Harry Hupp
United States District Court
312 North Spring
Los Angeles, California 90012

The Court of Appeal - Second District
3580 Wilshire Blvd.
Los Angeles, Ca. 90010

88-611

Supreme Court, U.S.
FILED
SEP 17 1988
JOSEPH F. SPANIOL, JR.
CLERK

NO. _____

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1988

TIMOTHY SCOTT ROMAN
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF LOS ANGELES
Respondent

THE PEOPLE OF THE STATE OF CALIFORNIA, BY THEIR ATTORNEY, IRA REINER, THE DISTRICT ATTORNEY FOR THE COUNTY OF LOS ANGELES
Real Party in Interest.

APPENDIX B TO: PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF CALIFORNIA

TIMOTHY SCOTT ROMAN
(PRISONER 8875112/Hall of Justice)
In propria persona
c/o CHESTER LEO SMITH
12301 Wilshire Blvd. #303
Los Angeles, CA 90025
(213) 476-6486

APPENDIX B TABLE OF CONTENTS

B-1 to B-5	NIH PUBLICATION NO. 86-2793 May, 1986
B-6 to B-9	**Potential Epidemic ....** New England Journal of Medicine September 19, 1985
B-10 to B-18	7th Report CJD PHS Committee
B-19 to B-28	Neurology, 1987. **Iatrogenic** **Creutzfeldt-Jakob Disease** Elizabeth Rappaport, M.D. (Attached to CJD PHS Report)
B-29	First Page. CDC Solicitation contract (awarded to Westat Inc.

B1

NIDDK Fact Sheet

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
National Institute of Health
NIH Publication No. 86-2793
May 1986

HUMAN GROWTH HORMONE AND CREUTZFELDT-JAKOB DISEASE

Why was the distribution of Human growth hormone made from human pituitary glands stopped?

In late February and early April of 1985, Government health officials were notified that first one, and then two more men in their twenties and mid-thirties who had been treated years before with human growth hormone (hGH) had died. Before their deaths, the three men had symptoms of a neurologic disorder called Creutzfeldt-Jakob disease (CJD). Pathologists confirmed this diagnosis in

all three cases by careful microscopic examination of brain tissue from the men.

All three men had received hormone through the National Hormone and Pituitary Program or NHPP. The NHPP is a program funded by the ... (NIDDK), a part of the Federal Government's National Institutes of Health (NIH). In the early sixties, the NHPP was set up to provide a central coordination center for the collection of pituitary glands removed at autopsy and for the distribution of hGH and other hormones extracted from these glands. An estimated total of approximately 10,000 patients have been treated with the NHPP-distributed growth hormone. After reports of three deaths from CJD in this patient group it was virtually certain that the men who died

had been exposed to CJD in growth hormone, and the NHPP stopped distribution of the hormone . . .

What is Creutzfeldt-Jakob disease?

Creutzfeldt-Jakob disease or CJD is a nervous system disease. It is transmitted by a particle similar to a virus. This particle, or infectious "agent," is different from the viruses most of us are familiar with. In fact, it has not yet been isolated and characterized. Unlike most "conventional" viruses, a person exposed to the CJD agent may harbor the agent for many years before becoming ill. For that reason, diseases like CJD are called "slow-virus" diseases.

What are the effects of CJD?

. . . . The following symptoms are

among those that may be seen in CJD. Changes in an affected person's behavior and mental capacity occur that may include erratic or aggressive behavior, progressive memory loss and confusion . . . . **CJD is always fatal.**

Is there any treatment for CJD?

There is no treatment that will cure or slow the progress of CJD.

Why is there any reason to believe that CJD is associated with growth hormone?

CJD is extremely rare. Worldwide, there is about one case per year per million population, and nearly all of these cases are in older individuals. Prior to the reports of CJD connected with growth hormone, there had been only 9 cases of the disease ever reported in

patients younger than 30 years old.

Because CJD is so rare in younger people, the chances of CJD occurring by coincidence in 1 year in 3 out of 10,000 individuals who received growth hormone are vanishingly small (1 in 1 trillion) .... Pituitary glands yield only small amounts of growth hormone. Hundreds or thousands of glands are needed to make one batch of hormone ....

Is there a diagnostic test for CJD?

No.

. . . . . .

B 6

POTENTIAL EPIDEMIC OF CREUTZFELDT-JAKOB DISEASE FROM HUMAN GROWTH HORMONE THERAPY

Paul Brown, M.D.; Carleton Gajdusek, M.D:
C.J. Gibbs, Jr., M.D; and David M. Aser, M.D.

A DECADE after the demonstration that Creutzfeldt-Jakob disease could be accidentially transmitted from one person to another during brain or eye surgery, iatrogenic Creutfeldt-Jakob disease has reappeared as a result of earlier therapy with human growth hormone, with the ominous possiblity of a burgeoning epidemic.

Within just a few months, three young adults in the United States have died from the disease, confirmed neuropathologically in two patients and clinically detected but unconfirmed in one, an additional neuropathologically

confirmed case has been identified in Great Britain . . . .

Creutzfeldt-Jakob disease has a worldwide yearly incidence of about one case per million population in countries where physicians are fully aware of the diagnosis and where it has been vigorously sought. However, only nine previous cases in patients under thirty years of age are known among more than three thousand worldwide cases either reported in the literature or referred to us for experimental transmission studies and three of these cases were iatrogenic. The age-specific mortality rate for Creutzfeldt-Jacob disease in the population under forty years of age is only 0.01 case per million . . . .

Experimental assessment of the level

of infectivity likely to be present in lots of human growth hormone already produced is also in progress. The manufacturing protocols used to produce the hormone are being duplicated with inclusion of known amounts of Creutzfeldt-Jakob disease virus, and the end product is being inoculated into thousands of laboratory animals . . . .

We are once again dramatically reminded that human tissues are a source of infectious disease, and that any therapeutic transfer of tissue from one person to another carries an unavoidable risk of transferring the infection . . . .

Doctor D. Carleton Gajdusek is one of the authors of this article. He is a Nobel Laureate.

INTRODUCTION

This is the seventh report of the Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease, which was established on May 29, 1985 . . . . The Committee has sought to pursue the goals of the Public Health Service, as outlined in the first report, related to the occurrence of Creutzfeldt-Jakob Disease (CJD) in recipients of human growth hormone (hGH) from the National Hormone and Pituitary Program (NIHPP) . . . .

Agency	
National Institute of Diabetes and Digestive and Kidney Disease	
Representative	
Dr. Phillip Gordon, Chairman	
Dr. Pierre Renault	
Dr. Ernest Johnson	
Dr. Judith Fradkin	
National Institute of Neurological and Communicative Disorders and Stroke	
Representative	
Dr. Paul Brown	
Dr. C.J. Gibbs, Jr.	
National Institute of Child Health and Human Development	
Representative	
Dr. James Mills	
Dr. Gilman Grave	
Centers for Disease Control	
Representative	
Dr. Mary Guinan	
Food and Drug Administration	
Representative	
Dr. James Bilstad	
Dr. Paul Parkman	

The Epidemiology Study

The purpose of the Epidemiology Study is to identify the cohort of recipients of NHPP growth hormone and conduct periodic surveillance of each patient to ascertain health status over the course of several years. The contract for the Epidemiology Study is funded jointly by NIDDK and the National Institute of Child Health and Human Development. The project officer is from the Centers for Disease Control; co-project officers are from the NIH, the CDC, and the FDA. The contractor is Westat, Inc. . . . .

Phase I: The purpose of Phase I is to conduct a rapid response study using the National Hormone and Pituitary Program and the National Death Index data sources

to define more precisely the study cohort and determine the number of deaths, by each cause, and the ratio of deaths, which have occurred in recipients of hGH.

Phase II: The focus of Phase II is to develop the study forms, data collection instruments, and analytic procedures for Phase III.

Phase III: The objectives of Phase III are to determine the incidence of CJD in the hGH patient cohort, to determine the asssociation of CJD with specific lots of hGH, to develop information on other important medical issues relevant to patients with hypopituitarism, and to determine other important long-term results of hGH treatment including ultimate height and social development.

Phase IV: During Phase IV, patients

or their proxies (a patient, spouse, etc.) will be contacted to determine if any symptoms of CJD develop after the Phase III interview . . . .

Phase III of the study began in January 1988 . . . .

Blood, Tissue, or Organ Donations by nGH Recipients . . . .

On September 14, 1987, NIH convened a meeting to bring together representatives of the same three blood banking organizations, a virologist in the National Institute of Neurological and Communicative Disorders and Stroke, and officials from OASH, FDA, CDC, and FIDDK. The decision was made that pituitary hGH recipients should be excluded from blood donation. Blood banking and FDA officials made plans for

a follow-up meeting to determine how this recommendation should be carried out.

. . . .

Following is the approach agreed upon . . . .

Update the fact sheet to include an appropriately phrased advisory that nGH recipients should not be blood or tissue donors . . . .

Provide information ... to the endocrinologists who treated patients with nGH. . . .

Assemble a panel of endocrinologists who would be able to counsel people ... after receiving the letter and fact sheet. . . .

At this time the volume and nature of the response from the parents and patients regarding blood donations are unpredictable. For some patients and families, the letter advising against blood and tissue donations may be the first time they have heard of the risk of CJD related to receiving growth hormone

. . . .

Tab I contains a review article on iatrogenic CJD which was written by Dr. Elizabeth Rappaport . . . .

IATROGENIC CREUTZFELDT-JAKOB DISEASE

Elizabeth B. Rappaport, M.D.

[Former FDA ... medical officer ...]

Creutzfeldt-Jacob disease (CJD) is a rare, transmissable, fatal neurodegenerative disorder that occurs primarily in people aged over fifty years. The CJD pathogen is resistant to chemical and physical methods commonly used for decontamination and sterilization. The mode of transmission of naturally occurring CJD is not understood. A small fraction of cases are familial, but familial transmission does not appear to be an important source of infection with the agent. There is little evidence that family members or spouses of affected persons are at increased risk of developing CJD.

However, iatrogenic transmissions of CJD are well documented. Several patients have developed CJD following surgical procedures. One received a corneal transplant from an affected donor, and two others were exposed to intracranial electrodes that had previously been used in a CJD patient. Two cases have been linked to a neurosurgical operating theater in which a patient with known CJD had had burr holes for ventriculography several weeks earlier. Recently, CJD was diagnosed in a patient who had received a **dura mater** graft nineteen months before the onset of symptoms. In addition to these documented iatrogenic events associated with neural or ocular tissue, CJD has been transmitted to laboratory animals from the blood and urine of

affected patients. Thus, blood and urine could also be vehicles for person-to-person transmission of CJD.

Scrapie is a neurodegenerative disorder of sheep that is similar to CJD in humans . . . . CJD has been transmitted by neural and non-nueral tissue of patients clinically ill with CJD. By analogy to the experience with scrapie as well as to the observations in laboratory animals deliberately infected with CJD, it can be inferred that blood and tissues of affected humans may be capable of transmitting the agent of CJD before the development of frank manifestations of the disease. If so, the risk of iatrogenic spread of CJD would be proportional to the prevalence of

potentially infectious people in the population. This prevalence can be estimated as the product of the annual incidence of CJD and the duration of infectivity. Since CJD is uniformly fatal, annual mortality may be taken as an estimate of the annual incidence. In the United States, one-hundred and forty-two deaths from CJD were recorded in 1980. The duration of CJD infectivity is not known, but may be considerably longer than the duration of clinical disease. If one assumes, for example, a total of two years of infectivity, then the prevalence in the United States of potentially "infectious" individuals would be 284 (142 CJD cases per year x 2 years duration of infectivity). At the other

extreme, if one assumes thirty years infectivity, then the prevalence of potentially infectious individuals would be approximately 4,200 cases. If one takes an intermediate figure of ten years for the duration of CJD infectivity, the prevalence of potentially infectious individuals would be approximately 1,400.

In the United States, approximately eight percent of the population undergoes surgery annually. Using the intermediate figure of 1,400 potentially infectious people about 100 such persons would have a surgical procedure each year.

Operating rooms or surgical instruments used for neurosurgical or general surgical procedures in patients harboring the CJD agent may pose a risk to other patients subsequently exposed to

the same operating rooms or instruments. Epidemiologic support for this mode of transmisssion is provided by a case-control study of sixty CJD patients reported in Japan between 1975 and 1977. . . . . In view of the evidence that routine methods of decontamination do not eliminate the CJD agent from the hospital environment, **the major defense against significant iatrogenic spread may be the low prevalence of the disorder.**

However, between November 1984 and April 1985, three young men who had received human cadaver pituitary-derived growth hormone (pit-hGH) during childhood died of CJD. Recently, CJD has been documented in two additional patients who received pit-hGH . . . . In all these cases, pit-hGH is considered to have been

the vehicle for transmission of CJD. A estimated 10,000 U.S. children received pit-hGH between 1963 and 1985. Neither the prevalence of degenerative neurologic disease in pit-hGH recipients nor the risk that these patients may develop CJD can yet be estimated. **In practice, however, the prevalence of potentially infectious persons in the United States may have been increased by as much as 10,000. Depending on the duration of CJD infectivity, the potential increase in the prevalence of persons harboring the transmissible agent of CJD could be between two-fold and thirty-fold.** For the purposes of developing public health policy, it would be prudent to consider any patient exposed to pit-hGH as potentially harboring the CJD agent.

During the past ten years, the medical community, particularly neurologists, neurosurgeons, pathologists, and laboratory workers, have been concerned about iatrogenic spread of CJD. Guidelines for the precautions to be taken with patients known or suspected to have CJD were published in 1977 and amplified in 1982, 1984, and 1986. It is not known to what extent procedures to remove or inactivate the CJD agent have been incorporated into routine hospital practice.

Several recommendations follow:

1. The medical community should be reminded of the potential infectivity of tissue and body fluid obtained from patients with CJD and should be aware of the potential significant increase in the

prevalence of people who may be haboring the CJD pathogen.

2. Routine review procedures for decontamination and sterilization of surgical instruments and operating suites should be reviewed to determine whether they comply with current recommendations for inactivation of the CJD agent. Responsible hospital personnel should monitor compliance with these procedures. Because of CJD's long latency, survellance for a disease outbreak would not be effective in detecting failures in decontamination practices.

3. Epidemiologic studies of patients exposed to pit-hGH should include the surgical procedures performed in these patients during or after pit-hGH therapy. Data obtained will improve

estimates of the number of growth hormone recipients who have surgery.

4. Consideration should be given to prohibiting pit-hGH recipients from donating blood, tissue, or organs.

5. Regulations should be developed to minimize the chance of manufacturing biologic products from blood, tissue, or organs from individuals who may harbor the CJD agent.

OMB 0990-0115 _ DOC NO. 6473N

SOLICITATION, OFFER AND AWARD

3. Solicitation No.
200-86-0902 (P)

Issued by: Code

Centers for Disease Control
Procurement and Grants Office, NCB
Atlanta, Georgia 30305